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EXAMINER CHAPMAN, GINGER T				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/606,442

**Applicant(s)**

BARAN, GEORGE

**Examiner**

Ginger T. Chapman

**Art Unit**

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 64-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 64-77 and 81 is/are rejected.
- 7) ☒ Claim(s) 78-80 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

#### **Status of the claims:**

1. Claims 64-81 are pending in the application.

#### **Withdrawn objections:**

2. The objection to claim 73 for informalities, made of record in the previous Office action, is withdrawn in view of Applicant's amendment to the claim.
3. The objection to claims 77 and 81 as substantial duplicates, made of record in the previous Office action, is withdrawn in view of Applicant's remarks.

#### **Withdrawn rejections:**

4. The rejection of claim 79 under 35 USC 112, first paragraph, is withdrawn in view of Applicant's remarks.

### ***Claim Objections***

5. With respect to dependent claims 76 and 81:

Applicant is advised that should claim 76 be found allowable, claim 81 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claim 77 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brauner (US 5,803,078) in view of Solazzo (US 4,990,133).
7. With respect to claim 77, as best depicted in Figures 1 and 6, Brauner does not teach but fairly suggests a method of forming a catheter (10) for nebulizing a liquid with a gas (c. 2, ll. 12-25; c. 5, ll. 30-35), the catheter having closely spaced distal orifices (Figure 6: 40, 42; c. 9, ll. 20-22) comprising: providing a multilumen (12, 14) extruded polymer tubing (c. 15, l. 56); and a plurality of orifices (40, 42) being sized to nebulize a liquid delivered through one of the lumens (42) (c. 9, ll. 43-45; c. 9, ll. 20-25). Brauner explicitly teaches an apparatus associated with such a method wherein the structural features taught by Brauner as intended to perform the method of forming a catheter, but does not explicitly teach the steps themselves. It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the

method steps as set forth in claim 77 forming the device of Brauner with a reasonable expectation of success.

8. Brauner discloses the claimed invention except for heating a portion of the tubing.

Brauner, at c. 15, ll. 55-56, teaches the multilumen extruded polymer tubing may readily be formed by polymer manufacturing processes such as, inter alia, extrusion. Extrusion is known in the polymer art as a manufacturing process in which plastic material is melted and formed into a continuous profile and thermoformed, i.e. heated until soft, for molding into its final shape (See Wikipedia article, made of record in a previous Office action, for description of extrusion process). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to heat the polymer of Brauner according to known methods in forming its intended shape with a reasonable expectation of success.

9. Brauner discloses the claimed invention except for forming a j-shaped distal section in the tubing at a distal end of the catheter, wherein the tubing in the j-shaped distal section maintains a shape at rest that curves away from a longitudinal axis of the catheter. Solazzo, at c. 1, ll. 65-68, suggests forming a j-shape distal section in a catheter. As seen in Figure 1, Solazzo teaches forming a j-shaped distal section (14) at a distal end (12) of a catheter (10). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the catheter of Brauner as taught by Solazzo since Solazzo states, at c. 1, ll. 67-68, that the benefit of forming the catheter with this design is that affords the user the ability to control the rotation or movement of the catheter during insertion with both accuracy and ease.

10. With respect to claim 64-65, Brauner inherently discloses cutting the tubing at a distal end and forming plurality of orifices since the reference discloses a cut medical catheter having orifices as discussed *supra* with respect to claim 77.

11. With respect to claim 66 and 68, Brauner inherently discloses heating the tubing to a glass transition temperature and exposing the plastic tubing to high energy radiation to crosslink polymers since it is made by extrusion (See Wikipedia article, made of record in a previous Office action, for description of extrusion process).

12. With respect to claim 67, Brauner discloses the catheter is for use in the respiratory system (c. 5, l. 21).

13. With respect to claims 69-74, as best depicted in Figure 4, Brauner teaches graduated markings (112, 112') along the catheter to provide a method of determining a rotational orientation of the catheter (c. 12, ll. 5-10). Brauner teaches that the marks perform the substantially identical function of providing markers along the catheter allowing the user to determine the orientation and placement of the catheter. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the marks comprising either radiopaque or ultrasonically formed or co-extruded markings as claimed since in the instant case substitution of equivalent methods requires no express motivation, as long as the prior art recognizes equivalency. *In re Sienbentritt*, 152 USPQ 618 (CCPA 1967).

14. With respect to claim 75, Brauner discloses the claimed invention except for embedding a wire in a wall of the nebulization catheter. Solazzo, at c. 3, ll. 55-68, suggests embedding wires in a wall of the catheter. As seen in Figure 4, Salazzo teaches embedding wires (73, 75) in a wall of the catheter. Salazzo suggests the intended use of the wire is that the wire is useful to prevent

folding of the catheter during use however it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

15. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the catheter of Brauner comprising embedded wire in a wall as taught by Salazzo since known work in one field of endeavor may prompt variations of for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art.

16. With respect to claims 76 and 81, Brauner teaches at least a portion of the catheter is constructed of a compliant material (c. 15, l. 46).

*Allowable Subject Matter*

17. Claim 78 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

18. The following is a statement of reasons for the indication of allowable subject matter: The subject matter not found in the prior art is a j-shaped distal section maintained in an orientation such that a plurality of the catheter orifices point toward a proximal end of the catheter, in combination with the orifices nebulizing a liquid delivered through one of the lumens to form an aerosol gas delivered through another lumen. The closest prior art teaches the following:

19. Brauner '078: teaches forming a catheter comprising a plurality of orifices for nebulizing a fluid wherein the distal section of the catheter is maintained in an orientation having the plurality of orifices pointing substantially aligned with the distal end of the catheter such that high velocity gas flow exits its orifice to aerosolize liquid expelled from the liquid orifice such that the nebulized fine particles/spray is propelled in a distal/forward direction into a pulmonary passageway of a patient. Brauner does not teach forming a j-shaped distal section and does not teach maintain the orifices pointing toward a proximal end of the catheter.

20. Solazzo '133: teaches forming a catheter comprising a plurality of orifices at a j-shaped distal section, said j-shaped distal section is maintained during insertion for allowing the user the ability to control insertion and placement of the catheter. Once inserted, shape memory wires embedded in a wall of the catheter act in conjunction with slits in the wall to push away the distal end to create a straight line lumen and opening oriented toward the distal end of the catheter.



Solazzo does not teach maintaining the j-shaped distal section in an orientation having the plurality of orifices pointing toward a proximal end of the catheter.

21. The prior art does not teach or fairly suggest maintaining the j-shape in an orientation having the orifices pointing toward a proximal end of the catheter because this would cause the aerosolized liquid to be propelled “backwards” toward the proximal end instead of forward in the direction the catheter is advancing, toward the target pulmonary tissue.
22. Claims 79 and 80 are allowable as being dependent from claim 78.

#### ***Response to Arguments***

23. Applicant's arguments with respect to claims 64-81 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginger T Chapman/  
Examiner, Art Unit 3761  
2/19/08

/Tatyana Zalukaeva/  
Supervisory Patent Examiner, Art Unit 3761